DGH 3000B
ULTRASONIC A-SCAN
OPERATOR'S MANUAL

SYS.SBH REV. 12/98

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I. INTRODUCTION

Ultrasound is sound of a frequency level too high to be heard by the human ear; however, sensitive equipment can send and receive these ultrasonic impulses as well as analyze information about anything these impulses strike along their route of travel. Every time a sound impulse strikes an interface, some sound is reflected (bounces off), and some sound is refracted (passes through). The amount of reflected and refracted sound varies with the density of the interface it strikes. Reflected sound acts much like a rubber ball being thrown at a wall. Sound hitting an interface perpendicularly will reflect back along the same path that it approached (Fig. A). Sound hitting an interface at an angle will reflect at an angle away from the source (Fig. B). The refracted sound will continue on at a lesser amplitude because of reflected energy lost at the interface.

By means of sophisticated equipment, sound impulses can be sent and their reflections can be converted and displayed on a visual screen in the form of a linear display with spikes related to interfaces that the impulses intersected. By looking at the height (intensity) of the spike, one can predict the angle at which the sound is striking it (Fig. A & B).

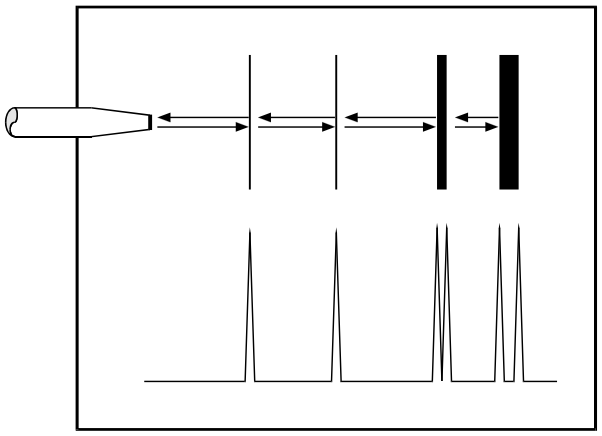


Figure A

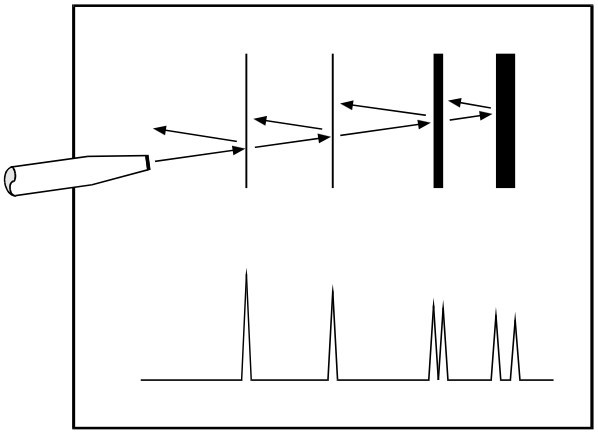


Figure B

Taking into consideration the above properties and applying them to ophthalmology, one can predict the alignment of an ultrasound beam through the eye. This alignment is crucial to the accuracy of measurements that will be used for IOL calculations. Fig. C illustrates an ultrasonic pattern typical when alignment along the visual axis is met. Please note the two high spikes representing the anterior lens and

posterior lens interfaces, along with a strong spike representing the retinal interface. Conversely, Fig. D illustrates a pattern representing misalignment. Improper measurements could be obtained with this incorrect alignment. Most older A-Scans require the operator to decide when proper alignment has been met. This is normally done by the operator looking at a display to view the spikes relating to the anterior lens, posterior lens, and retinal interfaces. This is very difficult to master when the operator's attention must be moved from the patient to the equipment. Reproducible results are particularly difficult between two or more operators.

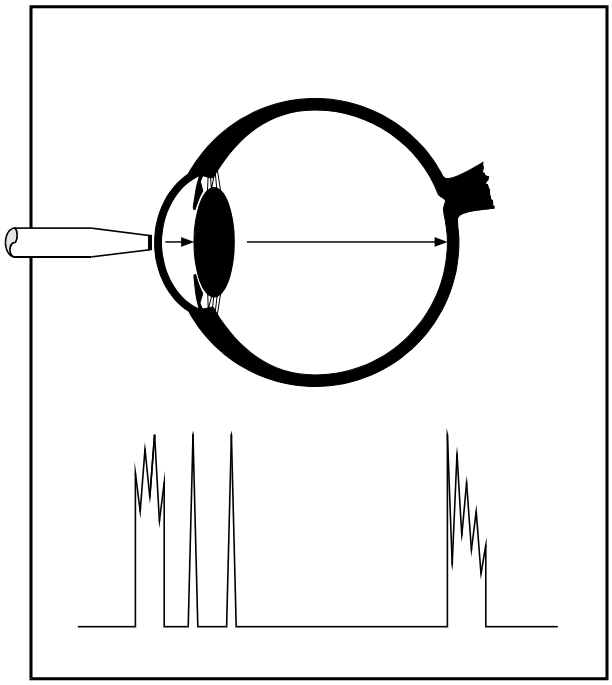


Figure C

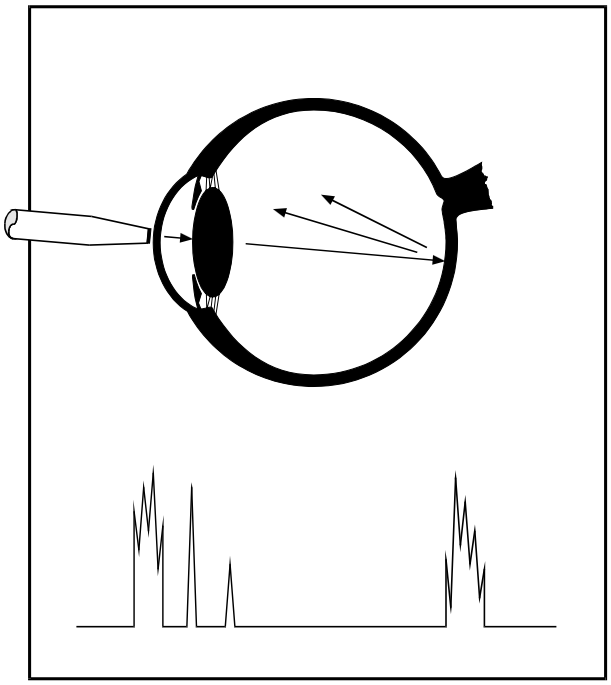


Figure D

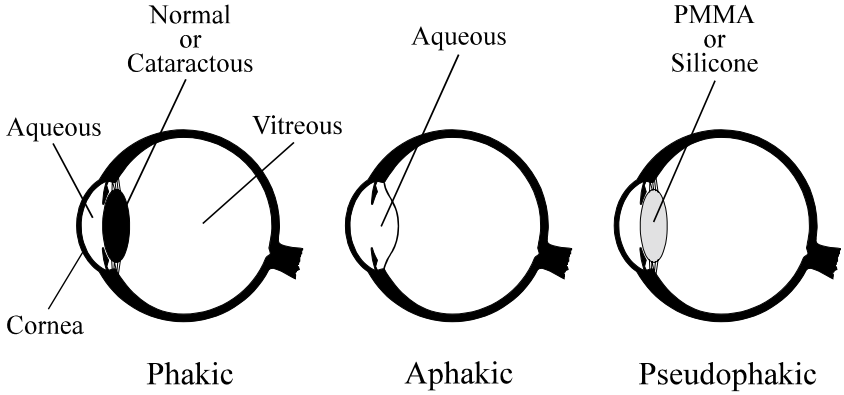
The DGH 3000B A-Scan incorporates a very sophisticated pattern recognition program that automatically checks for proper alignment. It looks for the proper pattern of spikes as well as going a major step further by looking at the retinal spike for particular signal characteristics which are produced only by retinal interfaces. This recognition is accomplished quickly (1,000 times per sec.) and without removing your attention from the patient.

Another important property of ultrasound is that it cannot travel through air. It must have a medium of substantial mass for transmission. Different materials or densities of materials will conduct sound at different speeds or velocities. Liquids or substances containing large amounts of water conduct ultrasound very well.

It has been proven that the following relationship exists: the denser the material, the faster sound is conducted through it. Using this relationship, Ophthalmic A-Scans can obtain distances in the eye by performing a two step process. First, a pulse of sound is timed as it travels through the eye, reflects off the retina, and returns to the transducer. Second, a length is calculated from the travel time by analyzing the time in comparison to the speed of sound through the eye.

It has been established that the speeds of sound for ophthalmic structures are as follows:

Cornea	1640 m/s
Aqueous	1532 m/s
Lens - Normal	1640 m/s
Lens - Cataractous	1629 m/s
Vitreous	1532 m/s
IOL PMMA	2760 m/s
IOL Silicone	1000 m/s

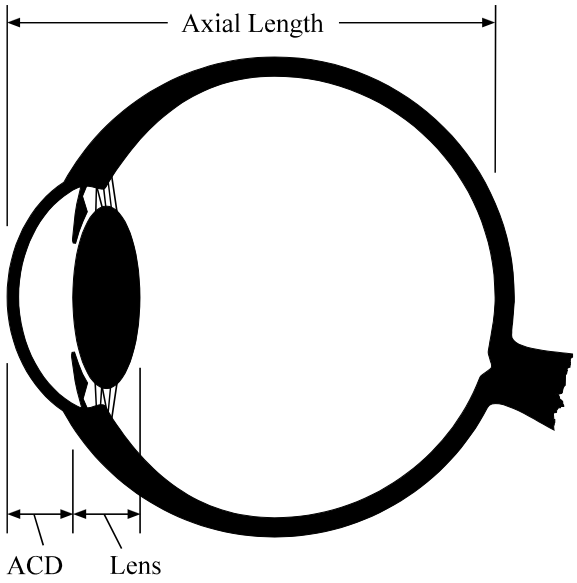


Most ophthalmic ultrasonic units use an average speed of sound of 1550 m/s for phakic eyes and 1532 m/s for aphakic eyes. The DGH 3000B is programmed to automatically use the proper speed for the eye you wish to read.

Another important area of concern in obtaining accurate measurements for IOL power calculating is corneal indentation. Logic would dictate that if you indent the very thing you are measuring, a false or shortened value will be obtained. Logic also dictates that as soon as you touch something that is soft, you will immediately indent it. This is true of the eye and corneal indentation. In recent years, other A-Scan manufacturers claimed that they can prevent corneal indentation by making their probes with soft water filled tips. This may have lessened indentation, but it fell short of eliminating it. The inconvenience and mess associated with water filled probes far outweighed their advantage.

Through a second pattern recognition program, The DGH 3000B will automatically disregard readings with corneal indentation present. So, through a simple and fast technique, accurate ultrasonic measurements can be obtained.

The only important measurement obtained via an A-Scan for IOL calculations is the axial length. Dimensions of other structural entities of the eye can prove useful; however, only a few A-Scans on the market are able to produce these. The DGH 3000B displays values for the anterior chamber, lens thickness, and axial length automatically each time a reading is made. These readings can be entered into the patient's permanent record via the optional printer or the optional computer link.



Obtaining accurate measurements for the axial length of the eye is only part of the challenge of predicting a correct IOL power for a patient. Many factors play roles in the procedure.

Axial Length

Axial length measurement is the most important factor affecting IOL power calculations. An error of 1.0 mm affects the post-operative refraction by approximately 2.5 diopters.

Corneal Power

Corneal power is the second most important factor affecting IOL power calculations. A keratometer is an instrument that measures the central 3.3 mm of the anterior curvature of the cornea in its two meridians. The readings are called K-readings.

There are two potential sources of error in keratometry. First, failure to calibrate the instrument can cause all readings to be in error by as much as 0.2 mm or 1.0 D. A second source of error is hidden in the dioptric scale of any keratometer. No keratometer measures the refracting power of the cornea in diopters. Keratometers measure the radius of curvature of the anterior corneal surface and then convert this millimeter measurement into diopters. The dioptric scale used for this conversion is based on an assumption, a fictitious refractive index. The true refractive index of the

cornea is 1.376, but to obtain an approximation of the true refracting power of the cornea from only the radius of the anterior surface, a fictitious refractive index has to be used. This index varies with the make of keratometer. Common values are:

1.3375	(Haag-Streit, Bausch and Lomb)
1.336	(American Optical)
1.332	(Gambs)

A radius of 7.8 mm will thus read 43.27, 43.08, or 42.56 D respectively, depending on which keratometer is used. These differences may not be of much importance in contact lens fitting or the determination of corneal astigmatism. However, these differences are significant when calculating IOL power, which is a new application for the established discipline of keratometry.

Any IOL power calculation formula which features the dioptric power of the cornea is subject to this source of error. With the same data, one may calculate IOL powers varying almost a diopter depending on the make of the keratometer used.

With both potential sources of error in mind, consider that an error of 1 diopter in the measurement of the corneal power produces an error of about 1 diopter in the postoperative refraction.

Postoperative Anterior Chamber Depth

The anterior chamber depth is the least important factor affecting IOL power calculations. An error of 1.0 mm affects the postoperative refraction by approximately 1.0 diopter in a myopic eye, 1.5 diopter in an emmetropic eye, and up to 2.5 diopters in a hyperopic eye.

Preoperative measurement of the anterior chamber depth is of little value, and the actual position of the IOL after surgery cannot be accurately predicted so an estimate has to be used.

Surgical Technique

Changes in corneal curvature are often noted postoperatively. This fact as well as differences between actual placement and predicted placement of the IOL can produce an error. An intraocular lens placed in the posterior segment requires a

stronger power, and inserting the implant with the convex side backwards necessitates an even stronger lens.

Implant Power

The implant power is measured differently by different manufacturers. This can result in variations between IOL companies.

Formulas Used

There are basically two classifications of IOL formulas - Theoretical and Regression. All THEORETICAL formulas work on optical formulas based on a two lens system, the cornea and pseudophakic lens focusing images on the retina. REGRESSION formulas are derived empirically from retrospective computer analysis of data on a great many patients who have undergone surgery. Although similar results are obtained between regression and theoretical formulas for eyes that are considered average in length (23.5 mm), results may vary for eyes on the shorter and longer side of average.

An ideal IOL prediction formula would be one that is derived empirically from a retrospective analysis of data on patients operated on by the same surgeon, using the same IOL, and obtaining measurements from the same equipment. This would be a personalized regression formula.

Summary

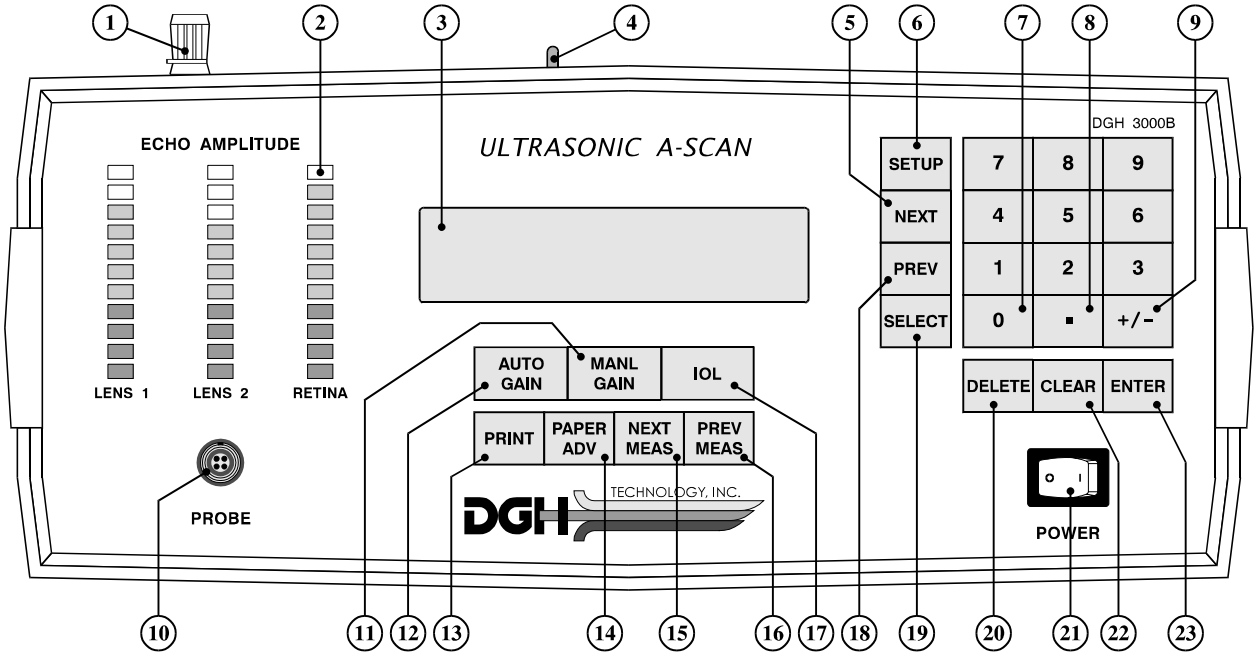
Predicting preoperatively the IOL power is a combination of science and art. Accurate axial length and keratometry measurements must be obtained. These measurements must then be applied to the prediction formula that works best for the surgeon. With the majority of accuracy based on correct axial length readings, the importance of a simple, fast and accurate ultrasonic A-Scan is increased.

II. FEATURES

The DGH 3000B A-Scan is manufactured with high quality components that are designed and built using the latest technological concepts. The result is an advanced and powerful A-Scan that offers practicality and reliability. The following features are just a sample of the characteristics and capabilities of this unique unit.

- Simple to use. No complicated setup procedures to follow - very user friendly.
- Solid transducer tip, 3.0 mm in diameter, for ease of applanation and visualization.
- Large thirty-two character alphanumeric display simultaneously displays anterior chamber depth, lens thickness, and axial length.
- Front panel keypad permits programming.
- Front panel LED bar graph for displaying echo amplitudes.
- Storage of measurement data for review.
- Operator feedback. An audible signal indicates when the probe is properly aligned and when a valid measurement is complete.
- Pattern recognition program yields accurate, reproducible measurements in a fraction of a second.
- Personalized configuration allows the operator to preset pertinent information that will automatically be used or inserted into the A-Scan function. This information is permanently stored even when the unit is turned off.
- Built in printer documents the A-Scan measurements and IOL power calculations generated by the unit.

Front Panel



① Paper Door Latch

When the thermal printer paper needs replacing, this latch is used to gain access to the twenty-eight column thermal graphics printer. The printer provides the operator with a permanent record.

② LED Bar Graph

The LED bar graph consists of three columns of multi-colored LED's used to indicate the amplitude of the anterior lens echo, posterior lens echo, and retinal echo respectively. Green LED's indicate the echo signal meets the measurement criteria. Orange LED's indicate the echo signal does not meet the lower limit criteria and red LED's indicate the echo has saturated, exceeding the upper limit criteria.

③ Display

The display consists of two lines of sixteen characters and is used to present information to the operator.

④ Paper Release

This lever releases the thermal paper from the printer platen.

⑤ **"NEXT" - Next Entry**

Used to advance to the next entry during the setup (configuration) of A-Scan or IOL parameters.

⑥ **"SETUP" - Setup (Configure)**

Used to initiate and terminate the setup (configuration) of A-Scan or IOL parameters.

⑦ **"0" through "9" - Digits**

Used to input appropriate numbers for IOL calculations and A-Scan setup.

⑧ **"." - Decimal Point**

Used to provide fractional data for IOL calculations.

⑨ **"+/-" - Sign Change**

Used to change the sign of the number appearing on the display.

⑩ **Probe Interface**

Connector located on the front panel which mates to the probe connector.

⑪ **"MANL GAIN" - Manual Gain Control**

Used to manually adjust the gain.

⑫ **"AUTO GAIN" - Automatic Gain Control**

Used to switch from one eye to the other during an A-Scan exam. Also used to return the unit to automatic gain control after being used in the manual gain control mode.

⑬ **"PRINT"**

Initiates print out.

⑭ **"PAPER ADV" - Paper Advance**

Allows the printer paper to be advanced.

⑮ **"NEXT MEAS" - Next Measurement**

Used to advance to the next measurement during the A-Scan measurement or IOL calculation review process.

⑯ **"PREV MEAS" - Previous Measurement**

Used to reverse to the previous measurement during the A-Scan measurement or IOL calculation review process.

⑰ **"IOL" - IOL Calculations**

Used to enable the IOL calculations.

⑱ **"PREV" - Previous Entry**

Used to reverse to the previous entry during the setup (configuration) of A-Scan or IOL parameters.

⑲ **"SELECT"**

Used to scroll through program options presented on the display.

⑳ **"DELETE" - Delete Measurement**

Used to delete an undesired measurement.

㉑ **Power Switch**

Rocker switch located on the lower right hand corner of the front panel.

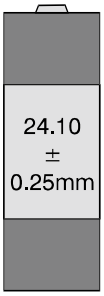
㉒ **"CLEAR"**

Used to clear all measurements from memory and prepare the unit for the next patient, or to clear unwanted entries presented on the display.

㉓ **"ENTER"**

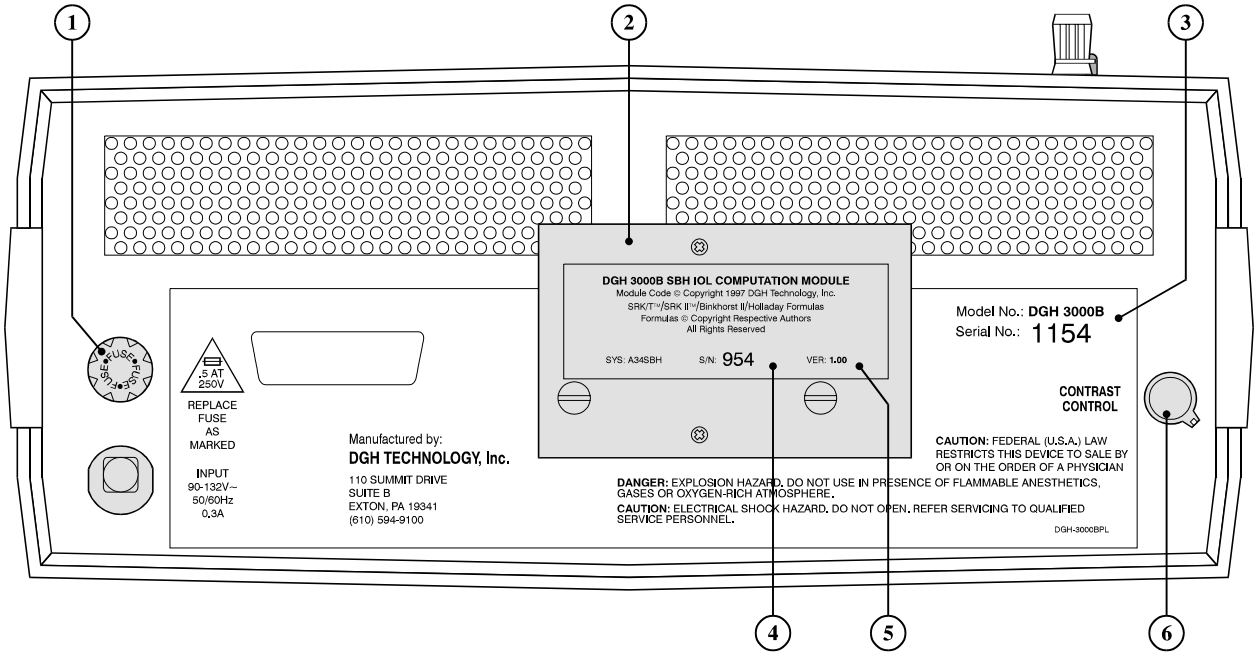
Used to accept options presented on the display. Also used to override the automatic gain control function.

Calibration Standard



Polystyrene block used to simulate aphakic axial length.

Back Panel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3
DGH 3000B SBH IOL COMPUTATION MODULE
Module Code © Copyright 1997 DGH Technology, Inc.
SRK/T™/SRK II™/Binkhorst II/Holladay Formulas
Formulas © Copyright Respective Authors
All Rights Reserved
SYS: A34SBH
S/N: 954
VER: 1.00
Model No.: DGH 3000B
Serial No.: 1154
CONTRAST CONTROL
.5 AT 250V
REPLACE FUSE AS MARKED
INPUT 90-132V~ 50/60Hz 0.3A
Manufactured by:
DGH TECHNOLOGY, Inc.
110 SUMMIT DRIVE
SUITE B
EXTON, PA 19341
(610) 594-9100
CAUTION: FEDERAL (U.S.A.) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN
DANGER: EXPLOSION HAZARD. DO NOT USE IN PRESENCE OF FLAMMABLE ANESTHETICS, GASES OR OXYGEN-RICH ATMOSPHERE.
CAUTION: ELECTRICAL SHOCK HAZARD. DO NOT OPEN. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.
DGH-3000BPL
4
5
6

① Fuse Holder

Contains the AC line fuse.

② IOL Calculation Firmware Module

Firmware module where the IOL calculation formulas are stored.

③ Unit Model Number & Serial Number

Location of the model number and serial number for the DGH 3000B. These numbers are used to identify the unit.

④ IOL Calculation Firmware Module Serial Number

Location of the serial number for the IOL calculation firmware module.

⑤ IOL Calculation Firmware Module Revision Number

Location of the revision number for the IOL calculation firmware module.

⑥ Contrast Control

Used to vary the contrast of the 32 character display located on the front panel.

IV. POWER-UP AND PROGRAMMING SEQUENCE

1. Plug the AC cord into a three prong outlet.
2. Verify that the probe is connected to the front panel.

> *** * * CAUTION * * ***
>
> When power is applied to the unit, the DGH 3000B will automatically set the internal gain of the unit to comply with the probe sensitivity. Therefore, it is **imperative** that the probe tip be **clean and dry before** the unit is turned on. Also, the temperature of the probe should be stabilized to within ±10°F of the temperature at which the probe will actually be used. **Never** turn on the unit with the probe attached after the probe has just been exposed to an extremely cold or hot environment. **Always** allow time for the probe to stabilize at room temperature.

3. Turn on the unit by using the power switch located on the front panel.
4. The unit will perform an internal self-test function and display the results. The display will also indicate whether or not an IOL Firmware Module is installed.
5. The DGH 3000B will automatically set the internal gain of the unit to comply with the probe sensitivity. This is how the unit maintains consistent performance throughout the life of a transducer.
6. When the initialization sequence is completed, the display will read:

SELECT EYE
OD

7. Use the "SELECT" key to display the proper eye: "OD" or "OS" (the default is "OD"). Press "ENTER" to confirm your selection. The display will read:

SELECT LENS TYPE
CATARACTOUS

8. Use the "SELECT" key to display the desired lens type: "Cataractous",

"Normal", "Aphakic", or "Pseudophakic" (the default is "Cataractous"). Press "ENTER" to confirm your selection. When the desired lens type is chosen, the appropriate program parameters for alignment criteria and velocity of sound are automatically installed so no further changes need to be made.

NOTE: If the pseudophakic lens type is selected, the display will prompt the operator to select an artificial lens type: "PMMA", "Silicone", or "Other".

The display will read:

1 OD(S) AUTO GAIN **NO MEASUREMENT**

9. This display indicates that the unit is now in measurement mode, i.e., the unit is ready to take measurements. Refer to Section V for a detailed description of the proper method for obtaining measurements.

V. A-SCAN MEASUREMENTS

1. Perform the Power-up and Programming Sequence as described in Section IV.
2. Position the unit for easy visibility during patient examination.
3. Seat or lay the patient in a comfortable position so that the head can be positioned in almost a horizontal plane. Use a firm, comfortable head rest to prevent unwanted head movement.
4. Anesthetize the cornea and ask the patient to fixate with their fellow eye on a spot on the ceiling or wall.
5. Hold the probe in such a way that you can stabilize your hand on the cheek or forehead of the patient. This will help prevent indentation of the cornea or excessive movement.
6. The probe can now be applanated to the cornea. This should be observed from a vantage point that allows the operator to look across the topography of the eye. This aids in seeing the exact moment when the probe touches the cornea so indentation of the cornea will not occur. Applanation should be made as close to the visual axis as possible. An aid in this can be to point the back side of the probe at the fixation target while touching the front portion to the center of the cornea.

   NOTE: When applanating the probe, one should be particularly careful that contact is made with the center of the probe tip.
7. At the moment of applanation, the unit will start to beep repeatedly at a rate of approximately two beeps per second. This means that proper coupling has been achieved and sound pulses are being transmitted through the eye. The display at this time will indicate "TAKING MEASUREMENT". If the beeping stops, this indicates that the probe is no longer applanated to the eye and a slight pressure of the probe should be applied.
8. If the probe is in proper alignment when applanation occurs, a measurement will be obtained almost instantaneously as indicated audibly by three short, successive beeps. The measurements will be shown on the display as follows:

LENS TYPE	DISPLAY MESSAGE
CATARACTOUS or NORMAL	1 OD(S) AXL = XX.XX AC = Y.YY LNS = Z.ZZ
APHAKIC	1 OD(S) AXL = XX.XX
PSEUDOPHAKIC	1 OD(S) AXL = XX.XX AC = Y.YY

where "1" indicates the measurements have been stored in memory location 1.

9. If the probe is not in proper alignment when applanation occurs, some minor adjustments may be needed. With the probe applanated, make some minor sweeping motions by moving the back portion of the probe in an X-Y plane. As the operator approaches the proper alignment along the visual axis, the repetition rate of the beeping sound will increase until a nearly constant tone is reached when proper alignment is obtained. During the alignment process, the LED bar graph will indicate the amplitude of the lens and retinal echoes being received. The criteria for proper alignment is that all echoes must be in the green section of the bar graph. Echoes in the orange section indicate that the amplitude is too low, while echoes in the red section indicate that the amplitude is too high.

10. As the unit reaches the maximum beep repetition rate, movement of the probe should be made in smaller and slower steps, so as not to pass through the area of proper alignment too quickly. As soon as proper alignment is achieved, the measurement will be obtained as indicated audibly by three short, successive beeps, provided there is no corneal indentation present. The display will indicate the measurement as shown in step 8.

11. If the beep rate reaches a constant tone during the alignment procedure, cornea indentation may be occurring. The DGH 3000B uses special circuitry that prohibits any measurements from being obtained if the cornea is being indented. If a constant tone is obtained, slowly withdraw the probe away from the cornea until the constant tone changes to pulsed beeping. Again, the pulsed beeping should be maximized as described in steps 9 & 10 until a measurement is obtained.

12. If a measurement is not obtained after a preset time period* of probe applanation, the unit will time out as indicated audibly by three short, successive beeps. The display will show a message indicating why a measurement was not obtained. Refer to Section VII for a list of the seven possible messages that will appear when no measurement is obtained and an explanation of each. At this point the operator should take the corrective action indicated by the display and reattempt taking a measurement.

***** The time duration allowed for a measurement cycle is preset at the factory for five (5) seconds. This time can be changed to meet the operator's needs. Refer to Section VI for the procedure used to change this time duration.

13. After obtaining an acceptable measurement for memory location 1, the unit will sense when the probe has been removed from the cornea and advance to memory location 2. At this point, the probe applanation and alignment procedures described in steps 5 through 11 should be repeated until a measurement is taken and stored in memory location 2.

14. The measurement and storage of up to eight (8) different readings for each eye is possible with the DGH 3000B, depending on how many measurements the operator feels is necessary to evaluate for consistency and repeatability.

15. All measurements can be reviewed by pressing the "NEXT MEAS" or "PREV MEAS" keys.

16. If during the data review a reading is observed which is suspect because it does not agree with the other measurements, the measurement data in that particular memory location may be replaced with a new measurement as follows:

    a) Scroll through the measurement data using the "NEXT MEAS" or "PREV MEAS" keys until the data which you desire to replace with a new measurement appears on the display.

    b) Press the "DELETE" key to delete the measurement from the display.

    c) Repeat the measurement sequence of steps 5 through 11 above until a new measurement is obtained.

17. After obtaining the desired measurements for the first eye (OD or OS), the operator may obtain measurements on the same patient's other eye, if desired, by pressing the "AUTO GAIN" key, selecting the eye and lens type for the second eye, and repeating the measurement sequence of steps 5 through 11.

    NOTE: The measurement data for the first eye will remain stored in memory while measurements are being obtained on the second eye.

18. After the desired measurements on one or both eyes are obtained, the operator may obtain a permanent record by pressing the "PRINT" key. The unit will print out the following:

    a) A header, which includes:

        i) Space to write the date, operator name, and patient name.
        ii) The eye measured (OD or OS).
        iii) The aqueous, vitreous, and lens velocities used in the ocular measurements.

iv) The lens type.

b) The actual ocular measurements including axial length, anterior chamber depth, and lens thickness where applicable. Up to eight (8) measurements for each eye may be printed out.

c) If enabled during the A-Scan setup mode (see Section VI), the print out will also include:

i) A graphic representation of the corneal, lens, and retinal echoes which occurred during the actual measurement.
ii) The average of the 1 to 8 measurements taken on each eye.

19. All measurements will remain in memory until the "CLEAR" key is pressed. Pressing the "CLEAR" key will clear all measurements from memory, retest the probe, and the display will indicate "SELECT EYE OD".

*** * * CAUTION * * ***

When the unit is CLEARED, the DGH 3000B will automatically set the internal gain of the unit to comply with the probe sensitivity. Therefore, it is **imperative** that the probe tip be **clean and dry before** the unit is cleared. Also, the temperature of the probe should be stabilized to within ±10°F of the temperature at which the probe will actually be used. **Never** clear the unit with the probe attached after the probe has just been exposed to an extremely cold or hot environment. **Always** allow time for the probe to stabilize at room temperature.

VI. SETTING UP THE DGH 3000B

Setup (Configuration) Overview

The DGH 3000B has been designed to allow the operator to set up certain default parameters to tailor the instrument to one's needs. These parameters are permanently stored in non-volatile memory and are automatically recalled from that memory each time the unit is powered up. The parameters which can be set up, or configured, in the DGH 3000B are:

1. The velocity of sound in aqueous/vitreous, cataractous lens, natural lens, PMMA lens, silicone lens, and a lens material which the operator identifies.
2. The thickness of PMMA lens, silicone lens, and a lens material which the operator identifies.
3. The measurement time duration.
4. The content of the print out.

Configuration Description

1. With the DGH 3000B in measurement mode, press the "SETUP" key and the display will read:

SELECT SETUP ASCAN

2. Press the "ENTER" key to begin the A-Scan setup mode. The display will show the first parameter and its factory default value:

AQUE/VITRE VEL 1532 M/SEC

Note: If the display indicates a velocity of sound other than 1532 m/sec, then the default value was previously changed by an operator.

3. Press "ENTER" if you wish to accept the velocity of sound that is currently being displayed. To change the velocity of sound, use the numeric keypad to select a new number, and then press the "ENTER" key to confirm the new number. The

display will advance to the next configurable parameter.

4. You may now configure the remaining parameters in a manner similar to step 3. Configuration values for any non-numerical parameters can be obtained by pressing the "SELECT" key. Always remember to confirm a new parameter value by pressing the "ENTER" key.

   The following table is a list of all A-Scan configurable parameters and their default values. These parameters are listed in the order that they appear during the A-Scan setup procedure.

Table 1 *Configurable Parameters For The A-Scan Setup Procedure*

Displayed Parameter With Default Value	Selection Choices	Description
AQUE/VITRE VEL 1532 M/SEC	1000 - 1629 m/sec	Aqueous/Vitreous Velocity
CTRCT LENS VEL 1629 M/SEC	1000 - 1999 m/sec	Cataract Lens Velocity
NATURAL LENS VEL 1640 M/SEC	1000 - 1999 m/sec	Natural Lens Velocity
PMMA LENS VEL 2760 M/SEC	1000 - 3999 m/sec	PMMA Lens Velocity
PMMA LENS THICK 0.50 MM	0.10 - 2.00 mm	PMMA Lens Thickness
SILICON LENS VEL 1000 M/SEC	100 - 1999 m/sec	Silicone Lens Velocity
SLCNE LENS THICK 0.15 MM	0.10 - 3.00 mm	Silicone Lens Thickness
OTHER LENS VEL 2760 M/SEC	1000 - 4000 m/sec	Other Lens Velocity
OTHER LENS THICK 0.50 MM	0.10 - 4.00 mm	Other Lens Thickness
ASCAN MEAS DELAY 5 SEC	1 - 30 sec	A-Scan Measurement Delay - when attempting to take a measurement, this is the length of time that the probe may be applanated to the cornea before a time out message appears.
WAVEFORM PLOT ENABLED	Enabled or Disabled	If this parameter is "Enabled", a Waveform Plot is added to the printout. This plot is a graphic representation of the corneal, lens, and retinal echoes which occurred during the actual measurement.
AVERAGE PRINTOUT ENABLED	Enabled or Disabled	If this parameter is "Enabled", the Average Printout is added to the printout. This average is computed from the 1 to 8 measurements taken on each eye.

5. After the “AVERAGE PRINTOUT” parameter has been entered, the display will read:

WRITING NVM PLEASE WAIT

for several seconds, and then the display will read:

1 OD(S) AUTO GAIN NO MEASUREMENT

At this point, the operator’s selected values for all parameters have been permanently stored in non-volatile memory and will not change (even when power is removed) unless deliberately changed by the operator by re-entering the A-Scan setup mode as described above.

NOTE 1: The “NEXT” and “PREV” keys may be used to advance and reverse, respectively, through the entries during the A-Scan setup procedure.

NOTE 2: The A-Scan setup procedure can be terminated at any point by pressing the “SETUP” key. At this point, the operator’s selected values for any parameters changed will be permanently stored in non-volatile memory.

VII. EXPLANATION OF DISPLAY MESSAGES

Display Messages Overview

The DGH 3000B provides feedback to the operator in the form of messages on the front panel display. These messages will appear if the operator has not been able to obtain a measurement after the probe has been applanated to the cornea for a preset time period. An audible feedback of three short, successive beeps will prompt the operator to remove the probe from the cornea and observe the display. The seven possible messages that can appear, with an explanation of each, is given below.

Display Message Descriptions

CHECK ALIGNMENT REATTEMPT MEAS

This message indicates that the probe was far out of alignment with the visual axis. The operator should make a major adjustment in probe orientation and reattempt measurement.

BAD RETINAL ECHO REATTEMPT MEAS

This message usually appears if the operator was close to having correct alignment but needed just a minor adjustment in probe orientation when the measurement time expired. The operator should reattempt the measurement with the probe oriented as close as possible to the final position of the previous measurement attempt.

BAD RETINAL ECHO ENTR TO OPEN LIM

OR

CHECK ALIGNMENT ENTR TO OPEN LIM

Either of these messages appears when the probe is properly aligned, but due to certain physiological conditions (blood in the vitreous, detached vitreous, cupping of the retina, etc.), the lens and/or the retinal echoes do not meet the normal limit criteria. If the operator does not intervene, the DGH 3000B will prompt the operator to reattempt another measurement at the normal limit criteria after a five second delay. If

the operator presses the “ENTER” key within the five second wait period as prompted by the “ENTR TO OPEN LIM” message, the limit criteria used to determine if valid lens or retinal echoes are present are opened up, i.e., it should be much easier to get a measurement. The display will then indicate “LIMIT OPENED” and prompt the operator to reattempt another measurement.

*** * * CAUTION * * ***

When the limit criteria are opened to allow measurements to be obtained more easily, it also increases the probability of obtaining a false measurement (measuring the distance to the sclera instead of the retina, measuring off axis, etc.). It is highly recommended that multiple measurements be obtained and the results evaluated to assure all readings fall within approximately ±0.2 mm. Measurements outside this range should be repeated so as not to be included in the measurement averaging. In any case, measurements obtained with the open limit criteria should be used for approximation purposes only.

CORNEAL COMPRESS
REATTEMPT MEAS

This message indicates the operator was pressing too hard on the cornea, possibly causing corneal compression or indentation when the measurement time expired. The operator should reattempt measurement being careful not to press too hard on the cornea.

NOTE: A constant audible tone indicates that corneal indentation may be occurring.

CORNEAL COMPRESS
ENTR TO OVERRIDE

This message occurs after the operator has received two (2) “CORNEAL COMPRESS REATTEMPT MEAS” messages. At this point the operator may disable (override) the test for corneal compression by pressing the “ENTER” key within the five second wait period as prompted by the “ENTR TO OVERRIDE” message. The display will then indicate “CMPRSSN OVERRIDE” and prompt the operator to reattempt another measurement. If the operator does not intervene, the display will prompt the operator to reattempt another measurement with the compression test still enabled after a five (5) second delay.

NOTE: When a measurement has been obtained with the compression test disabled, the DGH 3000B will automatically re-enable the compression test for the next measurement cycle.

*** * * CAUTION * * ***

When the compression test has been overridden, the probability of obtaining a short axial length measurement due to corneal compression or indentation is increased. It is highly recommended that multiple measurements be obtained and the results evaluated to assure all readings fall within approximately ±0.2mm. Measurements outside this range should be repeated so as not to be included in the measurement averaging. In any case, measurements obtained with the compression test overridden should be used for approximation purposes only.

GAIN TOO LOW
ENTR TO OVERRIDE

This message usually appears when the probe is properly aligned, but due to certain physiological conditions (extremely dense cataract, etc.), there is insufficient gain in the system to obtain a measurement. If the operator does not intervene within five seconds, the DGH 3000B will automatically increase the internal gain required to obtain a measurement on the next attempt. This will be indicated on the display as "AUTO GAIN ADJUST REATTEMPT MEAS". If the operator, however, suspects that the "GAIN TOO LOW" message was the result of a probe misalignment, the operator should press the "ENTER" key within the five second wait period as prompted by the second line of the display message "ENTR TO OVERRIDE". This will cancel or override the changing of the internal gain causing the message "AUTO GAIN OVRIDE REATTEMPT MEAS" to appear. At this point the operator may attempt another measurement.

NOTE: Since the "GAIN TOO LOW" message can appear as a result of probe misalignment, it is recommended that the operator override the automatic gain increase (press the "ENTER" key) the first time the "GAIN TOO LOW" message appears and then attempt another measurement. If the "GAIN TOO LOW" message then appears a second time, it can be assumed it is really a result of a physiological condition and the automatic gain adjustment should be allowed to take place.

VIII. MANUAL GAIN CONTROL

Manual Gain Control Overview

The DGH 3000B is preset at the factory with internal system gains that have been determined to be adequate to obtain measurements in most cases. Under certain conditions, however, such as an extremely dense cataract, these preset gains may prove to be inadequate. In this case, the operator may allow the automatic gain increase to take place as described in Section VII, or the operator may temporarily place the DGH 3000B in manual gain control as described below.

Manual Gain Control Description

1. The Manual Gain Control mode is entered by pressing the "MANL GAIN" key.
2. After pressing the "MANL GAIN" key, the display will indicate "SELECT EYE OD(OS)". Select the appropriate eye and confirm your selection by pressing the "ENTER" key.
3. The display will indicate "SELECT LENS TYPE". Select the lens type and confirm your selection by pressing the "ENTER" key.
4. The display will indicate "LENS 1 GAIN XX" where "XX" is the gain value that was preset at the factory for that particular lens type. The gain value "XX" is equal to the total system gain in decibels (dB) multiplied by two.
5. The operator can select a gain value other than that displayed by using the numeric keypad.
6. After the lens 1 gain value has been selected, the number is entered into memory by pressing the "ENTER" key. The display will now indicate "LENS 2 GAIN XX" where again "XX" indicates the gain value that was preset at the factory. Lens 2 gain can now be selected and entered in the same manner as lens l gain in step 5.
7. The display will now indicate "RETINA GAIN XX". The retinal gain can now be selected and entered in the same manner as the lens 1 and lens 2 gains.
8. After the retinal gain has been selected and entered, the display will indicate "N OD(S) MANL GAIN NO MEASUREMENT" where "N" is the number of the measurement that was being taken when the manual gain control mode was entered. A measurement may now be attempted.

9. Once the manual gain control mode has been entered, the DGH 3000B will begin all subsequent measurement attempts at the gains entered by the operator until either the “CLEAR” or “AUTO GAIN” key is pressed, or the power to unit is turned off and on.

   NOTE: The maximum gain values are 110 for Lens l, 200 for Lens 2, and 200 for the Retina.

IX. TEST BLOCK MODE

Test Block Mode Overview

The DGH 3000B uses a pattern recognition algorithm that looks for unique characteristics of the human retina to obtain true probe alignment. Therefore, it is not possible to simulate the echo response of the human eye using the standard multiple plastic interface phantoms. For this reason, the DGH 3000B must be placed into a test block mode to allow measurement of the plastic block used as a reference for calibration verification. The method of entering the test block mode and verifying the proper calibration of the DGH 3000B is described below.

Test Block Mode Description

1. The Test Block mode is entered by pressing the "SETUP" key simultaneously with powering on the DGH 3000B.
2. The display will indicate that the unit is in the "TEST/CALIBRATION MODE" for approximately two seconds and then show the normal initialization sequence.
3. The operator is then prompted to select the eye to be measured. Select and enter either eye.
4. The operator is then prompted to select the lens type. Select and enter the **"Aphakic"** lens.
5. The unit is now programmed to measure the plastic calibration reference block supplied with the unit.
6. Apply a small drop of water to the smaller diameter end of the reference block.
7. Applanate the probe tip to the center of the reference block. Note that the probe tip and reference block have equal diameters to facilitate positioning.
8. The DGH 3000B should measure the reference block almost instantaneously. If not, move the probe tip slightly until a measurement is obtained.
9. The readings obtained should be within the following limits:

   Axial Length: 24.10 ±0.25mm

10. Readings outside these limits do not necessarily indicate the DGH 3000B is out of calibration. Erroneous measurements may be due to the following:

    a) During the demonstration mode, the algorithm does not preclude

measurement of tear film as it does during normal operation. Therefore, if excessive water was placed on the reference block, it could be measured causing longer axial length measurements.

b) The plastic reference block is sensitive to temperature. The block must have stabilized at 72°F ±10°F before measurements are taken.

If an erroneous reading is obtained, verify that these fault conditions are not present and repeat the measurements on the reference block.

*** * * CAUTION * * ***

Upon completion of the calibration verification procedure, the unit **must** be returned to the **normal** operating mode by pressing the "CLEAR" key. **Never** attempt to take measurements on the eye when the unit is still in the test block mode. This could result in erroneous measurements.

11. If the reference block readings are outside the limits stated above, it is possible that the unit is defective and needs repair. Contact the Customer Service Department of DGH Technology, Inc. at (610) 594-9100 to arrange for return for repair.

X. DIAGNOSTIC MODE

Diagnostic Mode Overview

The DGH 3000B has the unique capability to provide diagnostic data to the operator and/or service personnel. This diagnostic data can be used in three ways:

1. As feedback to service personnel should any problem develop with the DGH 3000B.
2. As an aid to the operator to verify readings that may be suspect, such as readings on a pseudophakic eye where reduplication echoes may be present and be confused with the actual retinal echo.
3. As documentation of the actual ultrasonic echoes received by the unit.

Diagnostic Mode Description

1. The Diagnostic Mode is entered by pressing and holding the "PRINT" key until a second beep occurs and the printer starts printing.
2. If a measurement had been obtained, the beginning of the printout will include the measurement results plus a condensed plot of the ultrasonic echoes used to obtain the measurements. If no measurements had been obtained, it will be indicated on the printout.
3. Next the printout will include approximately 3½ inches of numeric printout. This data is used by service personnel for troubleshooting purposes.
4. Next the printout will include a high resolution graphic printout of the actual ultrasonic waveshape that the measurements were based on (if measurements had been obtained), or the waveshape that the unit was processing when the measurement cycle terminated.

   NOTE: The X-axis of the graphic printout is scaled for axial length in millimeters, allowing the operator to identify the peak of the retinal echo and obtain an axial length measurement.
5. The graphic printout can be terminated at any time by pressing the "CLEAR" key.

XI. SETTING UP THE DGH 3000B FOR IOL COMPUTATIONS

Introduction

The DGH 3000B, when equipped with an external Firmware Module (SYS: A34SBH), will perform four IOL formulas: SRK/T™, SRK II™, Holladay Dioptimum™, and Binkhorst II. These four IOL formulas have been proven over the years to have a high degree of accuracy in yielding the correct power of implant for individual eyes.

IOL Computation Setup Overview

Before IOL computations can be performed, the DGH 3000B must be set up, or configured, with the following parameters:

- IOL Configuration Number
- Printout Type
- IOL Computation Formula
- IOL Type
- IOL Anterior Chamber Depth (ACD)
- A-Constant
- Surgeon Factor
- Default IOL Configuration Number

The DGH 3000B allows the user to customize the printout and store constants for up to eight different lenses. This combination of printout design and lens constants is referred to as an "IOL configuration".

IOL Computation Parameters

Table 2 (on the next page) describes the IOL computation parameters that must be entered into the DGH 3000B. These parameters are listed in the order that they appear during the IOL computation setup procedure.

Table 2 *IOL Computation Parameters*

Parameter	Selection Choices	Description
Configuration Number	1 to 8	Identification number of the IOL configuration being defined.
Printout Type	Short	Printout includes the patient data, lens constants, and resulting IOL calculations. Only gives the average of axial length measurements.
	Long	Same as "Short" format above, plus the values of each axial length measurement.
	With Waveform	Same as "Long" format above, plus actual A-Scan waveform.
Formula	SRK/T	The SRK/T™ (SRK/Theoretical) formula combines the optical theoretic formula elements of the Hoffer-Colenbrander and Binkhorst formulas with physiologic iris plane estimation and use of the familiar SRK™ A-Constants as lens descriptors.
	Holladay	The components of the three-part Holladay system are: (1) data screening criteria to identify improbable axial length and keratometry measurements, (2) the modified theoretical formula which predicts the effective position of the IOL based on the axial length and the average corneal curvature, and (3) a Personalized Surgeon Factor (PSF) that adjusts for any consistent bias in the surgeon's results, from any source, based on a reverse solution of the Holladay formula.
	Binkhorst	Binkhorst II - a theoretical formula that will correct for variations in postoperative anterior chamber depth due to axial length.
	SRK II	The Sanders, Retzlaff, Kraff SRK II™ formula is a regression formula based on the observed relationship between the preoperative variables (keratometer readings and axial length) and the actual implant power required to achieve emmetropia.
IOL Type	Posterior	Posterior chamber lens position.
	Anterior	Anterior chamber lens position.
IOL ACD	1.5 to 6.0	Anterior Chamber Depth. A numeric ACD value must be entered for each lens. Obtain the ACD which corresponds to the lens A-Constant from the table of ACD vs. A-Constants (see Table 3 at the end of this section).
A-Constant	100 to 125	A numeric A-Constant value, provided by the lens manufacturer, that must be entered for the particular lens being used.
Surgeon Factor	-4.0 to +4.0	A numeric value for the Surgeon Factor must be entered for each lens. Obtain the Basic Surgeon Factor from the IOL manufacturer or Table 3 at the end of this section, or calculate the Personalized Surgeon Factor (PSF) as described in Section XII.
Default Configuration Number	1 to 8	The number of the IOL configuration that the DGH 3000B will default to each time an IOL computation is performed.

Inputting the IOL Computation Parameters

The setup procedure for inputting the parameters for each IOL configuration is as follows:

1. Turn the unit on and wait until the display reads:

SELECT EYE OD

2. Press the “ENTER” key twice. The display will read:

1 OD AUTO GAIN NO MEASUREMENT

3. Press the “SETUP” key. The display will read:

SELECT SETUP ASCAN

4. Press the “SELECT” key to display “IOL Computations”. Press “ENTER” to confirm your selection. The display will read:

CONFIG NMBR N

5. Use the numeric keypad to assign a number “N” (1 thru 8) to the IOL configuration you are defining. Confirm your configuration number by pressing "ENTER". The display will read:

SELECT PRINTOUT SHORT

6. Use the “SELECT” key to display the type of printout desired: “Short”, “Long”, or “With Waveform” (the default is “Short”). Press “ENTER” to confirm your selection. The display will read:

SELECT FORMULA SRK/T

7. Use the "SELECT" key to display the formula of your choice: "SRK/T", "Holladay", "Binkhorst", or "SRK II" (the default is "SRK/T"). Press "ENTER" to confirm your selection. The display will read:

SELECT IOL TYPE POSTERIOR

8. Use the "SELECT" key to display the lens type: "Posterior" or "Anterior" (the default is "Posterior"). Press "ENTER" to confirm your selection. If "Posterior" is entered, the display will read:

POSTERIOR ACD 0.00

9. Obtain an ACD from the table of ACD vs. A-Constants (see Table 3 immediately following this procedure) and use the numeric keypad to enter the ACD. Press "ENTER" to confirm the ACD. The display will read:

POSTERIOR ACONST 0.00

10. Use the numeric keypad to enter the A-Constant provided by the lens manufacturer. Press "ENTER" to confirm the A-Constant. The display will read:

SURGEON FACTOR + 0.00

11. You must now enter the Surgeon Factor obtained by one of two methods: (1) a Basic Surgeon Factor may be obtained from the IOL manufacturer or from the table of A-Constants vs. Surgeon Factors (see Table 3 immediately following this procedure). (2) Compute a Personalized Surgeon Factor (PSF) as described in section XII.

*** * * CAUTION * * ***

Unless previously programmed, the Surgeon Factor will appear on the display with a default value of 0.00. **DO NOT** inadvertently enter 0.00 by pressing the "ENTER" key. **You must enter** either a Basic Surgeon Factor that corresponds to a given A-Constant, or enter a PSF that is based on postoperative refraction. *The entry of an improper Surgeon Factor will result in erroneous IOL calculations when using the Holladay formula.*

Use the numeric keypad to enter the Surgeon Factor. Press "ENTER" to confirm the Surgeon Factor. The display will read:

DFLT CONFIG NMBR N

12. Use the numeric keypad to enter the number "N" (1 thru 8) of the IOL configuration that you wish the DGH 3000B to default to each time an IOL computation is performed. It is suggested that the configuration number for the most frequently used lens be entered. Press "ENTER" to confirm the default configuration number. For approximately two seconds, the display will read:

WRITING NVM PLEASE WAIT

and then the display will read:

1 OD AUTO GAIN NO MEASUREMENT

All of the above values have now been permanently stored into non-volatile memory.

Note: The "NEXT" and "PREV" keys may be used to advance and reverse, respectively, through the entries during the IOL computation procedure.

Table 3 *Corresponding values for the A-Constant, Binkhorst ACD, and Surgeon Factor*

A	ACD	Surgeon Factor	A	ACD	Surgeon Factor	A	ACD	Surgeon Factor
114.0	2.63	-1.04	116.0	3.80	0.09	118.0	4.97	1.22
114.1	2.69	-0.99	116.1	3.86	0.15	118.1	5.02	1.28
114.2	2.75	-0.93	116.2	3.91	0.20	118.2	5.08	1.34
114.3	2.81	-0.87	116.3	3.97	0.26	118.3	5.14	1.39
114.4	2.86	-0.82	116.4	4.03	0.32	118.4	5.20	1.45
114.5	2.92	-0.76	116.5	4.09	0.37	118.5	5.26	1.51
114.6	2.98	-0.70	116.6	4.15	0.43	118.6	5.32	1.56
114.7	3.04	-0.65	116.7	4.21	0.49	118.7	5.37	1.62
114.8	3.10	-0.59	116.8	4.27	0.54	118.8	5.43	1.68
114.9	3.16	-0.53	116.9	4.32	0.60	118.9	5.49	1.73
115.0	3.21	-0.48	117.0	4.38	0.66	119.0	5.55	1.79
115.1	3.27	-0.42	117.1	4.44	0.71	119.1	5.61	1.85
115.2	3.33	-0.36	117.2	4.50	0.77	119.2	5.67	1.90
115.3	3.39	-0.31	117.3	4.56	0.83	119.3	5.72	1.96
115.4	3.45	-0.25	117.4	4.62	0.88	119.4	5.78	2.02
115.5	3.51	-0.19	117.5	4.67	0.94	119.5	5.84	2.07
115.6	3.56	-0.14	117.6	4.73	1.00	119.6	5.90	2.13
115.7	3.62	-0.08	117.7	4.79	1.05	119.7	5.96	2.19
115.8	3.68	-0.02	117.8	4.85	1.11	119.8	6.02	2.24
115.9	3.74	0.03	117.9	4.91	1.17	119.9	6.07	2.30

XII. THE HOLLADAY FORMULA AND THE PERSONALIZED SURGEON FACTOR

Introduction

Dr. Jack Holladay's article entitled, "A Three-Part System for Redefining Intraocular Lens Power Calculations" gives the theory of the formula and also describes the study showing the improved accuracy of the formula. (Copies of this article are available upon request from DGH Technology, Inc.)

As stated in the article, the three parts of the system are as follows:

1. The Holladay formula using the "Basic Surgeon Factor".
2. Calculation of the "Personalized Surgeon Factor". This is the advanced method which requires inputting patient refractions.
3. A data screening method developed to prevent over 90% of the "surprises".

Surgeon Factors

The "surgeon factor" is represented as the distance, in millimeters, from the aphakic (or pseudophakic) anterior iris plane to the effective optical plane of the implanted intraocular lens.

Basic Surgeon Factor can be calculated from the A-Constant provided by the lens manufacturer.

Personalized Surgeon Factor (PSF) is the final step in making the Holladay calculation as accurate as possible. The proper method for arriving at this optimum constant is to solve the Holladay formula in reverse using preoperative corneal and axial length measurements, implanted IOL power, and stabilized postoperative refraction. If this is done on at least ten patients, the factor will be personalized and reflect any consistent biases from any source.

Calculating The Personalized Surgeon Factor (PSF)

Calculating the PSF is a simple two step procedure in which the only requirement is that all aspects of the surgery must be kept constant. The A-Scan,

keratometer, surgical procedure, and IOL must all be the same for any given set of data used to calculate the PSF. You can calculate a maximum of eight PSF values, one for each configuration.

STEP 1 Collect Data

Using a minimum of ten cases, make a table of the following data collected from patient files:

- PATIENT NO.
- K1
- K2
- AXIAL LENGTH
- IOL POWER
- SPHERE
- CYLINDER

(A blank page of this table is provided at the end of this section)

K1, K2, and AXIAL LENGTH are the values used preoperatively to calculate the IOL power. The IOL POWER is the power of the lens actually implanted, irrespective of the degree of ametropia that you may have chosen to produce.

SPHERE and CYLINDER are from the postoperative refraction. These should be stabilized results with a 20/40 or better acuity.

STEP 2 Enter Data into the DGH 3000B

1. Turn the unit on and wait until the display reads:

SELECT EYE OD

2. Press the "ENTER" key twice. The display will read:

1 OD AUTO GAIN NO MEASUREMENT

3. Press and hold in the "IOL" key until the display reads:

COMPUTE PSF

and after approximately two seconds the display will read:

CONFIG NMBR
N

4. Use the numeric keypad to select the number "N" (1 thru 8) of the IOL configuration that you wish to use for this particular set of data. Confirm your selection by pressing "ENTER". The display will read:

MERG/ RPLC/ IMPRT ?
MERGE

5. Use the "SELECT" key to choose between "Merge", "Replace", or "Import" (the default is "Merge"). In general, you will select "Merge" because this command is used for entering new data, or adding data to a previous data base.

   Be cautious in using the "Replace" command. This command will erase all data in the configuration which you have chosen. It would be used, for example. if you were to abandon a lens and wanted to use the IOL configuration number for a new lens. If you choose "Replace" and enter 0 for the first K1, all data in that IOL configuration will be erased. If you enter new data after "Replace", all the old data will be replaced with the new data that you have entered.

   "Import" allows you to transfer data from one configuration to another. The DGH 3000B has this capability, but it is recommended that you contact the Customer Service Department for detailed instructions.

   Press "ENTER" to confirm your selection. The display will read:

C1 PREOP K1
0.00

6. This display prompts you to start entering your table of data with K1 for case #1. Proceed to enter your data at the prompts. To signal that you have entered all of the data, enter 0 for the next K1. The display will read:

PRT/ ED/ RV/ EX/ ABT
PRINT DATA

7. You have just entered your table. You should now check to be certain that there are no errors. This can be done in two ways. You may print the data by choosing "Print Data" and check the printout against your table, or you may review the data by choosing "Review Data" and go through each entry step by step by pressing 'ENTER".

If an error is found, choose "Edit" and enter the case number that is to be corrected. When you have made the corrections, the menu in step 6 will reappear.

At this point, you may either "Abort" or "Save and Exit". "Abort" erases all data entered in this succession. Assuming that all data entries are correct, you should "Save and Exit".

The display will now show a new PSF calculated from the current data base. Press "ENTER" to accept this PSF for Holladay IOL computations. Once the "ENTER" key is pressed, the PSF will be permanently stored as the new Surgeon Factor for the IOL configuration that was selected in step 4. After pressing "ENTER", the unit will return to the normal measurement mode.

NOTE: If you wish to change the calculated PSF (based on surgical experience or to re-enter the Basic Surgeon Factor), use the numerical keypad to input a new value and then press the "ENTER" key. Once the "ENTER" key is pressed, this new value will be permanently stored as the new Surgeon Factor for the IOL configuration that was selected in step 4.

If at a later time you wish to add more cases to the configuration, follow the above procedure. The new cases will be added to the existing data in a statistically correct manner.

Explanation Of The Printout From Step 7 Above

Each case that you have entered will be listed on the printout. In addition, the Surgeon Factor for each case will be shown. If one or more of the cases were statistically out of range, it will be excluded and will be marked EXCLUDED.

A summary of the cases just entered, of cases previously entered, and of the combined cases will be given on the printout. An average of each of the entered values and of the calculated Surgeon Factors are included. Each of these values is followed by a +/- number. This is the standard error of the mean (SEM) as explained in the article by Dr. Holladay. The SEM for the Surgeon Factor should be less than 0.20 as a 0.20 corresponds to an error in the calculated IOL power of 0.5 D. The way to reduce the SEM for the Surgeon Factor is to include more cases.

Data Screening To Prevent Surprises

Dr. Holladay's article has a section titled "Data Screening Criteria", which states that routine data screening is an essential ingredient for accurate IOL calculation. This screening identifies the majority of large refractive surprises preoperatively.

The DGH 3000B automatically screens input data and A-Scan measurements for statistically unlikely values and flags them with either two or three asterisks on the printout. The purpose of this screening is to alert the operator that the values being entered are suspect. The values may be correct, but they are out of the norm and should be repeated either because they are statistically unlikely or because there is an unlikely variation between operative and fellow eyes.

Definitions Of Screening Flags

K Values --- Repeat Measurement

** Indicates that the measured K values are substantially different from those of an average eye (less than 40 D or greater than 47 D).

*** Indicates the difference in the K values for the operative eye and for the fellow eye is equal to or greater than 1 D.

Axial Length --- Repeat Measurement

** Indicates that the axial length measurement is less than 22.0 mm or greater than 25.0 mm. Both long and short eyes have a greater possibility of error than average eyes and should be re-measured.

*** Indicates that the difference in the axial length between the operative eye and the fellow eye is equal to or greater than 0.3 mm.

Emmetropic IOL --- Repeat both K and Axial Length Measurements

** Indicates that the calculated IOL power for emmetropia is substantially different (greater than 3 D) from that of an average eye.

*** Indicates that the difference in the emmetropic IOL power for the operative eye and the fellow eye is equal to or greater than 1 D.

IOL Parameters --- Cross Check

*** Indicates that one of the values entered for A-Constant, ACD, or Surgeon Factor is not in agreement with the others. Check the values entered for these parameters and enter the correct values.

Table For Data Collected From Patient Files

Patient No.	K1	K2	Axial Length	IOL Power	Sphere	Cylinder

XIII. IOL CALCULATION INSTRUCTIONS

Introduction

After the IOL Computation Setup has been completed (as described in Section XI), the DGH 3000B is ready to perform IOL calculations. When equipped with the Firmware Module SYS: A34SBH, the DGH 3000B will perform four IOL formulas: SRK/T™, SRK II™, Holladay Dioptimum™, and Binkhorst II.

The calculated IOL powers are shown on the front panel display as well as on the printout. The content of the printout can be customized as described in Section XI. All printout formats show the calculated IOL powers for all four formulas on the same printout. In addition, the printout will include a table of the calculated IOL power versus desired postoperative refraction, plus four powers above and four powers below the selected IOL power (in half-diopter increments) for the primary IOL formula. This same table is shown on the display, with the half-diopter increments obtained via the "PREV" and "NEXT" keys.

*** * * IMPORTANT * * ***

The calculated IOL powers are *NOT to be interpreted as suggested or recommended implant powers on the part of DGH Technology, Inc.* The calculated IOL should be used as a guideline only. It is based upon the accuracy of the IOL formula used and the data entered. The final IOL implant power selection must be made by the surgeon, based on personal experiences and previous postoperative results.

Obtaining IOL Calculations

In order to obtain IOL calculations, you must enter the following information into the DGH 3000B for both the operative and fellow eyes:

1. K1 and K2 Readings
2. Axial Length Measurement

The steps for entering this information and obtaining IOL calculations are as follows:

1. Turn the unit on and wait until the display reads:

SELECT EYE OD

2. Use the "SELECT" key to display the eye being measured: "OD" or "OS" (the default is "OD"). Press "ENTER" to confirm your selection. The display will read:

SELECT LENS TYPE CATARACTOUS

3. Use the "SELECT" key to display the lens type of the eye being measured: "Cataractous", "Normal", "Aphakic", or "Pseudophakic" (the default is "Cataractous"). Press "ENTER" to confirm your selection. The display will read:

1 OD(S) AUTO GAIN NO MEASUREMENT

4. If you already have a valid axial length measurement, skip the remainder of this step and go to step 5. Otherwise, obtain and review A-Scan measurements on the operative and fellow eyes by following the steps of Section V (no printout is required).

   A-Scan measurements may be obtained on the fellow eye by pressing the "AUTO GAIN" key, selecting the appropriate eye ("OD" or "OS"), and then selecting the lens type for the fellow eye. If measurements are taken, the IOL calculation printout will include the average axial length of the fellow eye. **Measuring the fellow eye is <u>recommended</u> as an effective screen for suspect axial length measurements.**

5. Press the "IOL" key and release. The display will read:

COMPUTE IOL (HOLD FOR PSF)

   and then the display will read:

CONFIG NMBR N

where "N" is the number of the default IOL configuration selected in step 11 of Section XI.

6. Press "ENTER" if you wish to accept this default configuration. If you would like to change the configuration number to any other pre-defined IOL configuration, use the numeric keypad to select the appropriate number (1 thru 8) and then press the "ENTER" key. The display will read:

SELECT OPER EYE OD

7. Use the "SELECT" key to display "OD" or "OS" for the operative eye. Press "ENTER" to confirm your selection. The display will now read:

OPERATIVE EYE K1 0.00

8. Use the numeric keypad to enter the first keratometer reading for the operative eye. This value must be entered in diopters (337.5 / mm of radius = diopters). Press "ENTER" to confirm the number. The display will read:

OPERATIVE EYE K2 0.00

9. Use the numeric keypad to enter the second keratometer reading for the operative eye. This value, like the first K reading, must be entered in diopters (337.5 / mm of radius = diopters). Press "ENTER" to confirm the number. The display will now read:

OPERATIVE EYE AL XX.XX

10. If axial length measurements were taken in step 4, the display will show the average of measurements taken on the operative eye. However, if no measurements were taken in step 4, the display will show an axial length of 0.00. A length of 0.00 indicates that the operator must use the numeric keypad to enter a

valid axial length for the operative eye. Once a valid axial length is displayed, press "ENTER" to confirm the number. The display will read:

FELLOW EYE K1
0.00

11. Use the numeric keypad to enter the first keratometer reading (in diopters) for the fellow eye. Press "ENTER" to confirm the number. The display will read:

FELLOW EYE K2
0.00

12. Use the numeric keypad to enter the second keratometer reading (in diopters) for the fellow eye. Press "ENTER" to confirm the number. The display will read:

FELLOW EYE AL
XX.XX

13. If axial length measurements were taken in step 4, the display will show the average of measurements taken on the fellow eye. However, if no measurements were taken in step 4, the display will show an axial length of 0.00. A length of 0.00 indicates that the operator must use the numeric keypad to enter a valid axial length for the fellow eye. Once a valid axial length is displayed, press "ENTER" to confirm the number. The display will read:

DESRD REFRACTION
+ 0.00

14. If you wish to calculate for an IOL power that will produce a postoperative refraction other than emmetropia, use the numeric keypad to enter that value. A minus sign is produced by pressing the "+/-" key. If you wish to calculate for emmetropia, leave the value at zero. Press "ENTER" to confirm the number. The display will briefly show the selected formula and the value of its associated A-Constant, ACD, or Surgeon Factor for the particular lens being used. The display will then read:

IOL	REFRCTN
XX.XX	± Y.YY

where "XX.XX" is the IOL power for the selected postoperative refraction

"Y.YY".

15. If desired, use the "NEXT" and "PREV" keys to review on the display the four IOL powers (in approximately half-diopter increments) above and below the selected IOL power.

> *** * * CAUTION * * ***
>
> Reviewing the calculated IOL powers on the display should be used as a preliminary screen only. The display information does not include the data screening flags described in Section XII. To observe these screening flags, a printout must be obtained as described in the next step.

16. Press the "PRINT" key to obtain a complete printout of the IOL calculations and associated data. The following outline is a description of the printout. This outline is presented in the order that the data is printed.

    a) A header, which includes a space to write the date, operator name, and patient name.

    b) (Optional) Axial length measurements if the "Long" printout option was selected, or axial length measurements with waveforms if the "With Waveform" option was selected (see Section XI).

    c) Operative Eye information, including:

        i) OD or OS
        ii) K1 and K2 values
        iii) Axial Length (measured or entered)
        iv) Desired refraction
        v) Aphakic refraction

    d) Fellow Eye information, including:

        i) K1 and K2 values
        ii) Axial Length (measured or entered)

    e) IOL Computation information, including:

        i) Configuration number
        ii) Anterior or Posterior lens
        iii) The selected formula
        iv) The Surgeon Factor, IOL ACD, and A-Constant for the lens being used.
        v) The calculated IOL powers for emmetropia on the operative eye. Calculations using all four formulas are shown, with an asterisk

indicating the selected formula.

vi) The calculated IOL powers for emmetropia on the fellow eye. Calculations using all four formulas are shown, with an asterisk indicating the selected formula.

vii) The target IOL power, i.e., the IOL power required to produce the selected postoperative refraction. Calculations using all four formulas are shown, with an asterisk indicating the selected formula.

viii) A table of calculated IOL powers vs. refraction for the selected formula. This table includes the target refraction, indicated with an asterisk, plus four IOL powers (in half-diopter increments) above and below the target refraction.

ix) Data screening flags indicated by two or three asterisks on the right side of the suspect data. A description of the screening criteria can be found in Section XII.

17. After the printout is complete, the display will be cleared of the IOL versus refraction information. The display will then return to the measurement data that was previously shown before the IOL computation mode was entered.

18. All measurements, K-readings, and the desired refraction will remain in memory until the "CLEAR" key is pressed or the unit is turned off. Pressing the "CLEAR" key will clear this data from memory and prompt the operator to select the eye and lens type for the next measurement cycle.

XIV. IMPORTANT NOTES

Caution !

The probe is fragile and extreme care must be taken in its handling. Sterilize the probe with either cold soak or ethylene oxide only. **DO NOT AUTOCLAVE !**

Loading Paper Into Printer

1. When the printer paper is almost exhausted, a colored stripe will appear on the paper. This stripe reminds the operator to change the paper before it reaches the end of the roll.

> *** * * CAUTION * * ***
>
> ***A possible loss of data could occur if the paper runs out while the unit is printing.*** Never try to print if there is not enough paper on the roll. Always install a new roll of paper ***immediately*** when the colored stripe first appears.

2. To change the paper, loosen the paper door latch and raise the door.
3. Pull the paper release lever all the way forward to lift the print head off of the rubber platen. The lever is completely forward when it latches in the direction that is opposite from the normal/rest position.
4. Grab the old roll of paper and remove it from the unit. The paper beneath the platen should slide out easily.
5. Remove the plastic paper spool from the old roll of paper and then insert the spool through the center of the new roll of paper.
6. Install the spool/paper roll assembly into the slotted brackets in the instrument with the loose end of the paper coming from underneath the paper roll. Push the paper roll assembly all the way down until it bottoms.
7. Insert the leading edge of the paper below the rubber platen, and push gently with a side-to-side motion until the edge of the paper appears on top of the rubber platen. Grasp the end of the threaded paper and pull approximately six (6) inches of paper through the thermal head area.

8. At this point, ensure that the paper is centered on the rubber platen and aligned properly. When correct alignment has been confirmed, grasp the leading edge of the paper and hold it toward the front of the instrument. Close and secure the paper door.
9. Return the paper release lever to the normal/rest position.
10. Confirm that the paper is feeding correctly by pressing the "PAPER ADV" key. When you are satisfied that threading has been satisfactorily accomplished, excess paper may be removed by using the paper tearing edge.

*** * * IMPORTANT * * ***

In the event the paper does run out during a printout, the message "OUT OF PAPER CORRECT OR CLEAR" will appear on the display. The operator then has two choices:

1. Press the "CLEAR" key which will clear the unit from the print mode and return the unit to the state it was in prior to printing.
2. Install a new roll of paper as described in steps 2 through 9 above. Upon completion of step 9 (returning the paper release lever to the normal/rest position), the printer will immediately continue printing from the point prior to running out of paper.

Service

Should service be necessary, contact the customer service department at:

DGH Technology, Inc.
110 Summit Drive, Suite B
Exton, PA 19341
Phone: (610) 594-9100
Fax: (610) 594-0390

XV. WARRANTY

DGH Technology, Inc. "DGH" warrants each new DGH 3000B and its accompanying accessories (hereinafter called "Equipment") to be free from defects in material and workmanship for twelve (12) months from the date of delivery to the original purchaser. This warranty is not applicable to any defect which is the result of an accident, misuse, mishandling, neglect, improper installation, improper repair or improper modification by persons other than DGH. This warranty does not apply if the Equipment has not been operated and maintained in accordance with the operating and maintenance manuals and instructions or bulletins issued in respect thereof by DGH. It is further understood that the cost of servicing replaceable and expandable items including parts and labor made in connection with the routine maintenance services as described in such Operator's Manual is not covered under this warranty and is the responsibility of the purchaser.

This warranty is strictly limited to replacement or repair of the part which is found to be defective in material and workmanship. At the option of DGH, said part shall be replaced or repaired free of charge, F.O.B. our factory by DGH.

DGH reserves the right to make changes in the design and material of Equipment without incurring any obligations to incorporate such changes in Equipment already completed on the effective date of any such change or changes.

This is the only warranty of this product and is expressly in lieu of all other warranties, expressed or implied by law or otherwise, including any implied warranties of merchantability and of fitness for a particular purpose. Without regard to the alleged defect, DGH does not, under any circumstances, assume any responsibility for the loss of time, inconvenience or other consequential damages, including but not limited to, loss of damage of personal property, or loss of revenue. DGH has neither assumed nor authorized any other person (including any distributor authorized to sell its Equipment) to assume for it any other liability in the connection with the sale of Equipment.

XVI. SPECIFICATIONS

Shipping Weight	15 pounds
Weight	12 pounds
Height	5.5 inches
Width	12.5 inches
Depth	12.0 inches
Power	100-120 or 200-240 VAC, 50-60 Hz
Probe Length	2 inches
Probe Diameter (Handle)	0.25 inches
Probe Diameter (Tip)	0.135 inches
Probe Frequency	10 +1.5 MHz
Accuracy	0.1 mm
Resolution	0.01 mm